

UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

18M2/1124

PATRÉA L PABST ARNALL GOLDEN & GREGORY 2800 ONE ATLANTIC CENTER 1201 W PEACHTREE STREET ATLANTA GA 30309-3450

APPI	LICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	20 7 5 6	DATE MAILED
	08/458.978	06/02/95	019	NAFF, D	1808	11/24/97
First Name Applicant	d EDELMAN.		ELAZ	ER R.		

TITLE OF INHIBITION OF VASCULAR SMOOTH MUSCLE CELL PROLIFERATION WITH IMPLANTED NVENTION MATRIX CONTAINING VASCULAR ENDOTHELIAL CELLS (AS AMENDED)

	ATTY'S DOCKET NO.	LASS-SUBCLASS BAT	CH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
	1 MIT6584	424-093.7	00 U4	45 UTILI	TY YES	\$660.00	02/24/98
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THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. <u>THIS STATUTORY PERIOD CANNOT BE EXTENDED.</u>

HOW TO RESPOND TO THIS NOTICE:

- I. Review the SMALL ENTITY status shown above.
 If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
 - A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
 - B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.
- II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.
- III. All communications regarding this application must give application number and batch number.

 Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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SERIAL NUMBER FILING DATE FIRST NAMED APPLICANT ATTORNEY DOCKET NO. 08/458,978 06/02/95 **EDELMAN** MIT6584

18M2/1124

EXAMINER

PATREA L PABST ARNALL GOLDEN & GREGORY 2800 ONE ATLANTIC CENTER 1201 W PEACHTREE STREET ATLANTA GA 30309-3450 👙

NAFF, D

ART UNIT PAPER NUMBER

DATE MAILED:

NOTICE OF ALLOWABILITY

1. If This communication is responsive to
PART.II.
A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).
Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED. APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER. a. □ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No
b. [] The proposed drawing correction filed on has been approved by the examiner. CORRECTION IS REQUIRED.
c. Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED. d. Formal drawings are now REQUIRED.
Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.
Attachments:
Examiner's Amendment Notice of Informal Application, PTO-152
Examiner Interview Summary Record, PTOL-413 Notice re Patent Drawings, PTO-948
Reasons for Allowance Listing of Bonded Draftsmen
_ Notice of References Cited, PTO-892 Other Information Disclosure Citation, PTO-1449

JAVID M. NAFF Primary Examined Art Unit 182%

01/07/1998 EKURTZ 00000065 DAM:012507 01 FC;216_37 (REV. 4-85) 1.00 CH

USCOMM-DC 89-3789

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An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In the title, cancel "OCCLUSION FOLLOWING INTERVENTION" and insert
-- SMOOTH MUSCLE CELL PROLIFERATION WITH IMPLANTED MATRIX CONTAINING
VASCULAR ENDOTHELIAL CELLS --;

page 24, line 3, cancel "Invention" and insert -- Disclosure --; Cancel the abstract (lines 4-16) and insert the following abstract

A composition and method are provided for inhibition of vascular smooth muscle cell proliferation following injury to the endothelial cell lining of a blood vessel such as resulting from angioplasty, vascular bypass surgery or organ transplantation. The composition is a matrix such as a biodegradable hydrogel made of a synthetic polymer, protein or polysaccharide seeded with vascular endothelial cells which can be xenografts, allografts or autografts, or genetically engineered Attachment of cells to the matrix can be enhanced by coating with collagen, laminin, fibronectin, fibrin, basement membrane components or attachment peptides. Biologically active compounds such as anti-inflammatory agents may also be contained in the matrix. In the method, the matrix containing endothelial cells is implanted in a patient at a site adjacent the injury such as by wrapping the matrix around the blood vessel. The endothelial cells secrete products that diffuse into surrounding tissue but do not migrate to the endothelial

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cell lining of the blood vessel. The endothelial cells may be obtained by biopsy of the patient into which the matrix is implanted and the cells can be cultured in the matrix in vitro and then implanted in vivo.

Applicants' representative, Patrea L. Pabst, authorized the following amendments on 11/18/97 during a personal interview:

Claim 1,

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line 2, after "vessel" first occurrence, insert -- having an endothelial cell lining --, and cancel "vascular tissue in a region" and insert -- the endothelial cell lining --;

line 6, before "endothelial", both occurrences, insert -- vascular --, and change "vascular tissue" to -- the endothelial cell lining --;

line 8, before "endothelial" insert -- vascular --, cancel
"arterial" and insert -- endothelial cell --, and after "lining" insert
-- of the blood vessel --;

Claim 6, line 3, cancel "carbohydrates, and";

Claims 8 and 18, line 5, cancel "and", first occurrence, and insert -- factors, --;

Claim 11,

line 2, after "vessel" first occurrence, insert -- having an endothelial cell lining --, and cancel "vascular tissue" and insert -- the endothelial cell lining --;

lines 4 and 5, before "endothelial" insert -- vascular --;

line 6, before "endothelial" insert -- vascular --, change "cell" to -- cells --, and cancel "arterial" and insert -- endothelial cell --

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line 7, after "lining" insert -- of the blood vessel --;

Claim 15, line 1, change "1" to -- 11 --;

Claim 16, line 3, cancel "carbohydrates,";

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Claim 18, line 5, before the period insert -- , and combinations thereof --.

An extension of time under 37 CFR 1.136(a) is required in order to make the above an examiner's amendment which places this application in condition for allowance. During the above noted interview conducted on 11/18/97, applicants' representative, Patrea L. Pabst, requested an extension of time for a second one MONTH(S) and authorized the Commissioner to charge Deposit Account No. 01-2507 the required fee of \$145.00 for a small entity for this extension.

The information disclosure statement filed 10/21/97 fails to comply with the provisions of MPEP § 609 because a certification has not been provided which is required in addition to a fee after final rejection (37 CFR 1.97(d). It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements. See MPEP § 609 ¶ C(1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be

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reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

The fax phone number is (703) 305-3014 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DMN 11/18/97 DAVID M. NAFF
PRIMARY EXAMINER